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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/870,009 | 05/30/2001 | Hisashi Kashima | JP920000069US1 | 8419 |

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| EXAMINER | |
|---|---|
| SMITH, CAROLYN L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | |

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/870,009 | KASHIMA ET AL. | |
| | Examiner | Art Unit | |
| | Carolyn L. Smith | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *5,8-12,15,17-27 and 30-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 8-12, 15, 17-27, and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5172004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's amendments and remarks, filed 3/3/05, are acknowledged. Amended claims 5, 8, 11, 15, and 17 and new claims 31-34 are acknowledged.

Applicant's arguments, filed 3/3/05, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims herein under examination are 5, 8-12, 15, 17-27, and 30-34.

### *Claim Rejections - 35 USC § 112, first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 32 recites a "portion which is other than said gene portion comprises a portion of said DNA which does not store a protein code sequence and transcription control information for said sequence" which does not appear to have adequate support in the specification, claims, and drawings, as originally filed. On page 13, lines 3-6, of the specification, states "a gene portion wherein a protein code sequence and its transcription control information are stored, and a

portion wherein genetic information is not included". This statement does not provide written support for the "portion which is other than said gene portion" mentioned in new claim 32 because this portion on page 13 merely states that genetic information is not included. "Genetic information" and "protein code sequence and its transcription code information" differ in scope. It is also noted that one of skill in the art would recognize "genetic information" to include nucleotides which may be present in the "portion which is other than said gene portion" such that genetic information is actually included. Because the introduction of the phrase "portion which is other than said gene portion comprises a portion of said DNA which does not store a protein code sequence and transcription control information for said sequence" does not appear to have adequate support in the specification, claims, and drawings, as originally filed, this phrase is considered to be NEW MATTER. This rejection is necessitated by amendment.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5, 8-12, 15, 17-27, and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dollinger (P/N 5,451,505) in view of Beremand et al. (P/N 4,888,282).

This rejection is necessitated by amendment.

Dollinger describes nucleic acids which are used as taggants that allows for subsequent identification of a substance, product identity (col. 1, lines 11-16 and 25-27) which represent a correlation with source identification information (as stated in instant claim 27) and watermark sequences (as stated in instant claim 30). Dollinger describes a taggant as a nucleic acid that comprises a specific nucleotide sequence or composition (col. 2, lines 59-62). Dollinger describes any substance may be used for tagging by treating the substance with a nucleic acid taggant (col. 1, lines 50-54). Dollinger describes amplification of a nucleic acid sequence of a taggant, if present, to determine if the specific nucleic acid sequence is present (col. 1, lines 60-65) which represents a nucleic acid sequence including a taggant. Dollinger describes tagging any substance with a nucleic acid taggant so that the nucleic acid attaches to the material (col. 1, lines 50-54). Dollinger describes the nucleic acid taggant comprises a specific nucleotide sequence or a composition of specific nucleotides to facilitate tracing or determining the origin or source of a material (col. 1, lines 54-60 and col. 3, lines 7-8) which represents identifying a source and source identification information, as stated in instant claim 5. Dollinger describes the nucleic acids can be either naturally occurring or synthetically derived (col. 2, lines 6-7) which represents a nucleotide sequence not naturally occurring in DNA (as stated in instant claims 5, 8, 11, 12, and 15), as well as not being naturally generated through gene mutation (as stated in instant claim 23), intentionally designed (as stated in instant claim 8), and produced by artificial, intentional manipulation (as stated in instant claim 33). Dollinger describes the taggants are typically non-biologically functioning and are not part of a functional nucleic acid sequence operating in a living cell (col. 2, lines 62-65) which is reasonably interpreted to mean the taggant sequence does not affect transmission of biologically functional genetic information (portion

including no genetic information. Dollinger describes living organisms contain unique nucleic acid sequences either natural or artificially introduced (col. 2, lines 65-67). Dollinger describes using combinations of sequences and varying levels of specific sequences to identify the product, product's origin, the lot or batch, or an identifier for a unit of commerce (col. 3, lines 22-28) as well as using a sequence with multiple regions of specificity (col. 5, lines 9-11) which is reasonably interpreted to encompass multiple patterns at predetermined locations, as stated in instant claims 9, 10, 18, 19, and 20. The instant specification, page 1, second paragraph, defines "value-added genes" as having properties or values rated and levels assigned and creating added value to the gene. Dollinger describes tracking animals and plants (gene bearing organisms) (col. 1, lines 17-19) which is reasonably interpreted to be determining product identity for cultivation or breeding purposes including value-added genes, as stated in instant claim 17. Dollinger describes amplifying the sequence prior to detection via polymerase chain technology (col. 2, lines 3-5) which is reasonably interpreted to mean being copy tolerant, as stated in claim 21. Dollinger describes the nucleic acids may be bound to solid support (devoid of genetic information and predetermined location) that is then mixed with the material being tagged (col. 2, lines 23-26), as stated in instant claims 15 and 26. Dollinger describes that the nucleic acid may be covalently bound to any one or all of the components of a material comprised of different components (col. 2, lines 19-22) which represents embedding at random locations, as stated in instant claim 22. Dollinger describes tagging methods involve detection and PCR technology where the nucleic acid must form duplexes with primers (complementary sequence) (col. 3, lines 41-47) and using hybridization techniques (col. 6, lines 3-20), as stated in claim 25. As instant claim 24 has been interpreted to require either a restriction enzyme identification or a promoter

but not both, Dollinger describes promoters (transcription control information) can be incorporated in the primers (col. 5, lines 47-51), as stated in claims 24 and 31. Dollinger describes use of a taggant of a sequence complementary to the DQα allele (gene) (col. 6, lines 55-56).

Dollinger does not teach a gene portion including a predetermined gene, protein code sequence, and gene portion is transcribed into RNA while the other portion is not transcribed.

Beremand et al. describe designing a synthetic gene which encodes for acyl carrier protein (ACP) and constructing, cloning, and expression in E.coli of spinach ACP-1 by appropriate expression vectors carrying the synthetic gene as well as predetermining the specific sequence (abstract and col. 4, lines 44-46) which represents a predetermined gene comprising a protein code, as stated in instant claim 31. Expression is defined by Beremand et al. as the transcription of a gene into messenger RNA and the subsequent translation of the mRNA into a protein coded by the gene (col. 3, lines 22-24) which represents transcribing into RNA, as stated in instant claim 34. Beremand et al. describe the gene is usually a component of larger synthetic recombinant DNA molecule including other DNA sequences (col. 4, lines 1-3) which represents a gene portion and other portions that may or may not be genes. Beremand et al. describe building in other sequences including restriction endonuclease recognition sites, promoters, enhancers, and the like into the constructions (col. 5, lines 3-11) which represents transcription control information of the sequence, as stated in instant claim 31. Beremand et al. describe a promoter as well as a NcoI site at the start codon designed into the synthetic ACP-1 gene (col. 10, lines 1-14) which represents transcription control information for said sequence. Beremand et al. describe a ribosome binding site upstream from the insert (col. 10, lines 6-7) which

represents a portion of DNA that does not store protein code sequence and transcription control information for said sequence as well as a portion other than the gene portion that is not transcribed, as stated in instant claims 32 and 34. Beremand et al. describe confirming identifications of ACP (col. 12, lines 3-7).

Dollinger states a method for tagging a material (any substance) by treating the material with a nucleic acid taggant so that said nucleic acid attaches to said material in an amount sufficient for subsequent detection (col. 1, lines 50-54). Dollinger states that one can detect far less taggant than ever before such that small levels are needed whereby tagged drugs can still pass FDA standards for the amount of DNA in any product (col. 1, lines 37-41). Beremand et al. state the expression of a plant ACP gene in a suitable vector might provide a means for providing sufficient ACP for enyzmological and other studies (col. 2, lines 18-20). Beremand et al. state analogous genes designed for expression of ACP in plants would be a useful tool for controlling fatty acid synthesis and metabolism (abstract). Beremand et al. state provide a synthetic ACP gene prototypes designed for expression in plants and animals (col. 2, lines 48-50). It would have been obvious to the person of ordinary skill in the art at the time the invention was made to add a taggant (as stated by Dollinger) to an expression vector containing a gene (as stated by Beremand et al.) in order to track the manufacture and distribution of natural resources such as animals and plants, as stated by Dollinger (col. 1, lines 17-20). The person of ordinary skill in the art would have been motivated to make this modification because the tagging aids in product identity and provides information useful to manufacturers and consumers, as stated by Dollinger (col. 1, lines 25-27). One of ordinary skill in the art would have expected success in this

modification as Beremand et al. state that the gene is usually a component of larger synthetic recombinant DNA including other DNA sequences (col. 5, lines 1-3).

Thus, Dollinger and Beremand et al. motivate the instant invention.

Applicants summarize the Dollinger reference. Applicants assert that Dollinger does not disclose various amended limitations now recited in the instant claims. These limitations can be found in the other reference used in the 35 USC 103 (a) rejection. Applicants summarize their invention. Applicants further summarize the Dollinger reference and state the purpose of the Dollinger reference. It is noted that the instant invention is a composition. The purpose of the instant invention as well as the Dollinger reference do not appear to affect the structural limitations of either composition. Applicants further mention amended limitations. These limitations can be found in the other reference used in the 35 USC 103 (a) rejection. Applicants state that "gene" is not mentioned in the Dollinger reference. It is noted that an allele (col. 6, line 56) is a gene.

***Formal Matters***

Applicants again requested that the IDS, filed 5/17/04, be considered. The last three documents listed in the IDS have been considered to the extent indicated by the degree of relevance stated by Applicants, filed 5/17/04. The first document in the IDS, filed 5/17/04, fails to comply with the provisions of 37 CFR 1.97, 1.98, and MPEP § 609, because it does not appear

to be a published document, and no place of publication or publisher has been provided. This reference have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609, C(1).

Applicants request an interview if the application is not in condition for allowance. The application is not in condition for allowance, so they are invited to call the Examiner to set up an interview if they so desire.

***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
5/3/05

May 2, 2005